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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/436,454	11/08/99	LIVAK	K 16842-760

021971 HM22/0124
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EXAMINER	
RILEY, J	
ART UNIT	**PAPER NUMBER**
1655	3

DATE MAILED: 01/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/436,454	LIVAK ET AL.
Examiner	**Group Art Unit**
Jezia Riley	1655

☒ Responsive to communication(s) filed on *Nov 8, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1* is/are pending in the application.

~~Of the above,~~ Claim(s) *2-40 are canceled* ~~is/are withdrawn from consideration.~~

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The art unit for this application has changed. Applicant is informed, that any future response should be directed to Art Unit 1655.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claim 1 is rejected under 35 U.S.C. § 112, 2nd paragraph.

Claim 1 is indefinite because it is unclear what "under condition for hybridization". It is unclear what are the specificity of the probe for hybridizing. Are the conditions of the hybridization considered high or low stringency conditions?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> *(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

> *b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

4. Claim 1 is rejected under 35 U.S.C. § 102(a) as being anticipated by Livak et al. (PCR Methods and Applications, pp. 357-362, 1995).

The Livak et al. reference discloses a probe that is an oligonucleotide with both a reporter fluorescent dye and a quencher dye attached. An increase in reporter fluorescence intensity indicates that the probe has hybridized to the target. Probes with a quencher dye attached to an internal nucleotide were compared with probes with the quencher dye attached to the 3'-end nucleotide. In all cases, the reporter dye was attached to the 5'-end. The fluorogenic probes consist of an oligonucleotide with a reporter fluorescent dye such as fluorescein, attached to the 5'-end; and a quencher dye, such as rhodamine (abstract). A series of probes with increasing distances between the fluorescein reporter and rhodamine quencher were investigated.

This rejection has been made because the authorship of the reference is different from the instant inventorship. One possible way of overcoming the rejection may be via a Katz type Declaration that explains the difference.

5. Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Bagwell (EPO 0 601 889 A2, 1994).

Bagwell discloses a probe comprising a oligonucleotide sequence and at least one donor label moiety and at least one acceptor label moiety. The label moieties are preferably fluorophores (abstract). These label moieties Q1, Q2, Q, and P are

described in page 4, lines 20-48. These probes are used for performing DNA or RNA hybridization assays. The use of luminescent labels therein discloses techniques in which the labeled probe exhibits different characteristics when associated with a target from those when unassociated (pages 3-4).

6. Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Lee et al. (Nucleic Acids Research, 1993, Vol. 21, No. 16, pp. 3761-3766).

The Lee et al. reference teaches probes that have fluorescent indicator dye at the 5'-end and a common quencher dye attached to the seventh nucleotide from the 5'-end. The probes generated fluorescence from its indicator dye only when the sequence between the indicator and quencher dyes was perfectly complementary to the target.

7. Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Heller et al. (EPO 0 229 943, 1987).

Heller et al. discloses fluorescent probes, for polynucleotide hybridization assays, comprising donor and acceptor fluorophores. Maximum observed acceptor fluorophore emission was also found to be dependent upon hybridization of the probe to its complementary target sequence (page 6, lines 29-31). With proper spacing (between the fluorophores) an exceptionally high value for fluorescent emission by the acceptor fluorophore can be obtained (page 6-7, bridging paragraph and page 7-8, bridging paragraph).

Fluorescein is a particularly desirable donor moiety. A list of other fluorophores is given on page 10 paragraph 2.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,876,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming the same method but not of the same scope.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is (703) 305-6855. The Examiner may normally be reached Monday through Friday, 0900 - 1700 EST. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Gary Jones, may be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix Receptionist whose telephone number is (703) 308-0196.

Any necessary fax can be sent to (703) 308-4242.

JEZIA RILEY
PATENT EXAMINER